

REMARKS

In view of the preceding amendments and the comments which follow, and pursuant to 37 CFR §1.111, amendment and reconsideration of the Official Action of August 30, 2001 is respectfully requested by Applicant. A clean copy of the claims currently pending, as now amended, are appended hereto for the Examiner's convenience.

Amendments to specification and claims

The specification has been amended to correct a typographical error on page 6.

Claims 30-34 have been cancelled without prejudice. Claims 29, 35-39, 41-45, and 47-48 have been amended. No new matter has been introduced. More specifically:

- Independent claims 29, 39, and 41 have been amended to incorporate the limitation from dependent claim 34. Claim 35 was revised accordingly.
- Support for deleting “-shaped” in the phrase “flat-shaped” in claims 29, 36-39, 41 and 47 can be found in the specification at page 10, lines 25-32 and page 12, lines 15-16 wherein, by looking at the objects that Applicant refers to as being “flat-shaped,” it is obvious that Applicant is referring to a flat surface when using the term “flat-shaped.”
- Support for replacing the phrase “covered by this part in the direction of curvature produced when the object is bent” with “when the test strip is bent towards a side on which the overlay is located” in claim 42 can be found in the specification on page 19, lines 4-29.

- Support for replacing the phrase “displaceable zones of an overlay comprising two elements” with “parts of the overlay elements that can be displaced freely relative to the strip surface” in claim 43 can be found in the specification on page 19, line 31 to page 20, line 2.
- Support for deleting the phrases replacing “displaceable regions” with “parts that can be displaced freely relative to the strip surface” in claim 44 can be found in the specification on page 19, line 31 to page 20, line 7.
- Support for replacing the phrases “of the two overlay elements is above the separation line between the” and “and preferably symmetrical thereto” with “covers” in claim 45 can be found in the specification on page 19, line 31 to page 20, line 2.
- Support for replacing the phrase “an analyte sample is distributed over the entire analyte sensitive region of the test carrier, the test strip is self-dosing and excess sample remains above the application spot” with “a sample excess is not taken up by the strip” in claim 48 can be found in the specification at page 37, lines 1-4.

#### Paragraph 1

The Examiner has quoted the second paragraph of 35 U.S.C. 112.

#### Paragraph 2

The Examiner has rejected claims 29-49 under the second paragraph of 35 U.S.C. 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) In claims 29, 36-39, 41 and 47, the Examiner explains that the term "flat-shaped" is indefinite since "flat" is used as a term to describe the texture of a surface and does not relate to shape.

For clarification, Applicant has amended claims 29, 36-39, 41 and 47 by deleting the term "-shaped."

(b) In claim 31, the Examiner explains that it is unclear what is intended by "the structure and proportion in the mixture of the R groups corresponds to the structure and abundance of such groups in natural fatty acids."

Applicant has now cancelled claim 31 without prejudice.

(c) In claim 42, the Examiner explains that what is meant by "surface can be displaced freely relative to the strip surface covered by this part in the direction of curvature produced when the object is bent" is unclear.

To overcome the rejection, Applicant has amended claim 42 by replacing "covered by this part in the direction of curvature produced when the object is bent" with "when the test strip is bent towards a side on which the overlay is located."

(d) The examiner observes that there is no antecedent basis for "the displaceable zones" in claim 43 and for "the displaceable regions" in claim 44.

To overcome the rejection, Applicant has amended claim 43 by replacing "displaceable zones of an overlay comprising two elements" with "parts of the overlay elements that can be displaced freely relative to the strip surface." Furthermore, Applicant has amended claim 44 by replacing "displaceable regions" with "parts that can be displaced freely relative to the strip surface."

(e) The examiner observes that there is no antecedent basis for “the separation line” in claim 45.

To overcome the rejection, Applicant has amended claim 45 by replacing “of the two overlay elements is above the separation line between the” and “and preferably symmetrical thereto” with “covers.”

(f) The examiner observes that there is no antecedent basis for “the analyte-sensitive region” or “the application spot” in claim 48.

To overcome the rejection, Applicant has amended claim 48 by replacing “an analyte sample is distributed over the entire analyte sensitive region of the test carrier, the test strip is self-dosing and excess sample remains above the application spot” with “a sample excess is not taken up by the strip.”

### Paragraph 3

The Examiner has quoted 35 USC 102(e).

### Paragraph 4

The Examiner has rejected claims 29, 30, 33, 35, 36, 39-42, 44, 46, and 49 under 35 USC 102(e) asserting that the Applicant’s invention is anticipated by Good et al. (US 6,194,224)(hereinafter “Good”).

Applicant has cancelled claims 30 and 33 without prejudice. Applicant draws the Examiner’s attention to the new claims set 29, 35-39, 41-45, and 47-48 now submitted, which claims incorporate the N-oleoyl-sarcosinate wetting agent limitation from non-rejected claim 34. Although Good teaches the use of fatty acid sarcosinates as wetting agents, Applicant’s N-oleoyl-sarcosinate cannot be “at once envisaged” from this general group of compounds. Good narrows the generic formula by stating that “[p]referably, the fatty acid has from about 10 to about 18 carbon atoms and

more preferably is a saturated fatty acid." However, the compounds falling within this category still encompass a vast number of species since fatty acids can differ greatly in degree of chain branching. Furthermore, as the Examiner acknowledges, "the preferred sarcosinate [in Good] is sodium myristoyl sarcosinate." A spreading material comprising a porous structure impregnated with an N-oleoyl-sarcosinate wetting agent is not envisaged in the Good reference and, therefore, Applicant's new claims now obviate the Examiner's rejection.

Applicant submits that his application is now in condition for allowance, and favorable reconsideration of his application in light of the above amendments and remarks is respectfully requested. Allowance of claims 29, 35, 36, 39-42, 44, 46, and 49 at an early date is earnestly solicited.

Paragraph 5

The Examiner has quoted 35 USC 103(a).

Paragraph 6

The Examiner has rejected claims 32, 37, and 38 under 35 USC 103(a). With respect to claim 32, the Examiner asserts that Applicant's invention is unpatentable over Good as "it would have been obvious to one of ordinary skill in the art to use a mixture of glycinate although such is not specifically taught."

Applicant has now cancelled claim 32 without prejudice.

With respect to claims 37 and 38, the Examiner asserts that "one of ordinary skill in the art would have been able to determine what size absorbant pads would be suitable for any particular diagnostic strip." To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is non-obvious.

Applicant draws the Examiner's attention to the new claims set 29, 35-39, 41-45, and 47-48 now submitted, which claims incorporate the N-oleoyl-sarcosinate wetting agent limitation from non-rejected claim 34. Applicant feels that new independent claims 29, 39, and 41 are patentable and, therefore, claims 37 and 38 depending therefrom are also patentable.

Furthermore, Applicant respectfully traverses the rejection by arguing that the Examiner has not established a *prima facie* case of obviousness. The Examiner asserts that “[o]ne of ordinary skill in the art would have been able to determine what size absorbant pads would be suitable for any particular diagnostic strip.” Applicant would like to draw the Examiner's attention to claims 37 and 38, which claims are directed to weight per unit area, thickness, and pore volume of the spreading material, and not size of the absorbant pads.

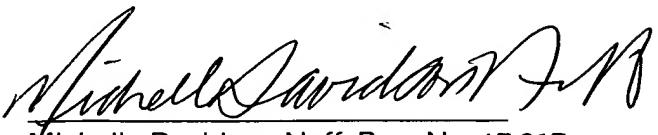
Good does not disclose the weight per unit area, thickness, or pore volume of the sample receiving zone material. Therefore, one of ordinary skill in the art would have to vary all parameters or try each of numerous possible choices to arrive at a successful result since Good gives no indication of which parameters are critical and no direction as to which of many possible choices is likely to be successful. Therefore, Applicant feels that the weight per unit area, thickness, and pore volume of the spreading material in Applicant's claimed invention is nonobvious in light of Good.

Applicant submits that his application is in condition for allowance, and favorable reconsideration of his application in light of the above remarks is respectfully requested. Allowance of claims 37 and 38 at an early date is earnestly solicited.

\* \* \* \* \*

The Examiner is hereby authorized to charge any fees associated with this Amendment to Deposit Account No. 50-0877. A duplicate copy of this sheet is enclosed.

Respectfully submitted,



Date: February 28, 2002

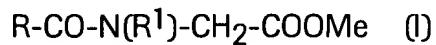
Michelle Davidson Neff, Reg. No. 47,817  
Roche Diagnostics Corporation  
9115 Hague Road, Bldg. D  
P.O. Box 50457  
Indianapolis, IN 46250-0457  
Phone: 317-521-2851  
Fax: 317-576-2883

G:\CORE\PLD\WORD\BMID\9600-9899\9826US\Amendment & Reply.doc



**Versions with Markings to Show Changes Made**

29. (Amended) A spreading material comprising a porous flat[-shaped] structure impregnated with a wetting agent, wherein the wetting agent is N-oleoyl-sarcosinate [comprises an N-acyl-glycinate of formula I]



in which R represents an aliphatic group with 9 to 23 carbon atoms, the aliphatic group being saturated or comprising one to three double bonds,

$R^1$  represents hydrogen or a lower alkyl group and

Me is hydrogen or a metal atom].

35. (Amended) The spreading material of claim 29 wherein the spreading material comprises 0.01 to 2.0 % by weight of [the] N-oleoyl-sarcosinate [acyl-glycinates of formula I] relative to the weight of the material before impregnation.

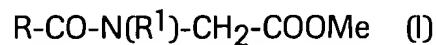
36. (Amended) The spreading material of claim 29 wherein the porous flat[-shaped] structure comprises a textile sheet material made of monofilaments or corresponding multifilament yarns.

37. (Amended) The spreading material of claim 29 wherein the porous flat[-shaped] structure comprises a fabric or fleece material with a weight per unit area of 10 to 200 g/m<sup>2</sup>.

38. (Amended) The spreading material of claim 29 wherein the porous flat[-shaped] structure has at least one of a thickness of 20 to 200 µm and a pore volume of 30 to 85%.

39. (Amended) A process for producing a spreading material comprising the steps of

providing a porous flat[-shaped] structure and impregnating the porous flat[-shaped] structure with a wetting agent, wherein the wetting agent is N-oleoyl-sarcosinate [comprising an N-acyl-glycinate of formula I]

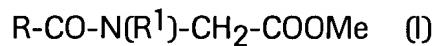


in which R represents an aliphatic group with 9 to 23 carbon atoms, the aliphatic group being saturated or comprising one to three double bonds,

$\text{R}^1$  represents hydrogen or a lower alkyl group and

Me is hydrogen or a metal atom].

41. (Amended) A test strip comprising a flexible flat[-shaped] support on which one or several test fields are arranged next to one another, wherein said test fields carry one or several detection layers stacked on top of one another, and wherein the test fields are covered by an overlay made of a spreading material comprising a porous flat[-shaped] structure impregnated with a wetting agent, wherein the wetting agent is N-oleoyl-sarcosinate [comprising an N-acyl-glycinate of formula I]

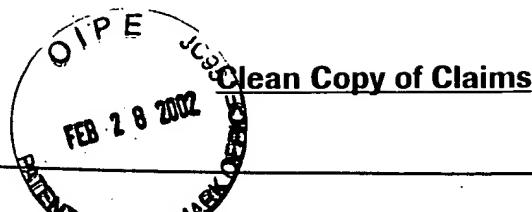


in which R represents an aliphatic group with 9 to 23 carbon atoms, the aliphatic group being saturated or comprising one to three double bonds,

$\text{R}^1$  represents hydrogen or a lower alkyl group and

Me is hydrogen or a metal atom].

42. (Amended) The test strip of claim 41 wherein the overlay comprises one or several flat-shaped overlay elements which are attached to the test strip in such a way that a part of their surface can be displaced freely relative to the strip surface when the test strip is bent towards a side on which the overlay is located [covered by this part in the direction of curvature produced when the object is bent].
43. (Amended) The test strip of claim 42 wherein the test fields are covered by the parts of the overlay elements that can be displaced freely relative to the strip surface [displaceable zones of an overlay comprising two elements].
44. (Amended) The test strip of claim 42 wherein the overlay comprises two overlay elements whose parts that can be displaced freely relative to the strip surface [displaceable regions] face one another and overlap.
45. (Amended) The test strip of claim 44 wherein the overlap [of the two overlay elements is above the separation line between the] covers two test fields [and preferably symmetrical thereto].
47. (Amended) The test strip of claim 41 wherein the arrangement of detection layers and overlays on the test strip is covered with an inert flat[-shaped] material in such a manner that a space only remains free that is adequate for sample application in an overlap region of the overlay elements viewed in the direction of the longitudinal axis of the test strip.
48. (Amended) The test strip of claim 41 wherein the hydrophilicity, transparency and liquid conducting capacity of the overlay material are matched in such a manner that a sample excess is not taken up by the strip [an analyte sample is distributed over the entire analyte-sensitive region of the test carrier, the test strip is self-dosing and excess sample remains above the application spot].



- sub C1 D1*
29. A spreading material comprising a porous flat structure impregnated with a wetting agent, wherein the wetting agent is N-oleoyl-sarcosinate.
- SJG 1 SJG 2*
35. The spreading material of claim 29 wherein the spreading material comprises 0.01 to 2.0 % by weight of N-oleoyl-sarcosinate relative to the weight of the material before impregnation.
36. The spreading material of claim 29 wherein the porous flat structure comprises a textile sheet material made of monofilaments or corresponding multifilament yarns.
37. The spreading material of claim 29 wherein the porous flat structure comprises a fabric or fleece material with a weight per unit area of 10 to 200 g/m<sup>2</sup>.
- B2*
38. The spreading material of claim 29 wherein the porous flat structure has at least one of a thickness of 20 to 200 µm and a pore volume of 30 to 85%.
39. A process for producing a spreading material comprising the steps of providing a porous flat structure and impregnating the porous flat structure with a wetting agent, wherein the wetting agent is N-oleoyl-sarcosinate.
40. The process of claim 39 wherein the wetting agent is applied such that a coating of 0.01 to 2.0% by weight of the applied wetting agent relative to the weight of the material before impregnation remains on the porous material.
41. A test strip comprising a flexible flat support on which one or several test fields are arranged next to one another, wherein said test fields carry one or several detection layers stacked on top of one another, and wherein the test fields are covered by an overlay made of a spreading material comprising a porous flat structure impregnated with a wetting agent, wherein the wetting agent is N-oleoyl-sarcosinate.

- Seq C1*
42. The test strip of claim 41 wherein the overlay comprises one or several flat-shaped overlay elements which are attached to the test strip in such a way that a part of their surface can be displaced freely relative to the strip surface when the test strip is bent towards a side on which the overlay is located.
43. The test strip of claim 42 wherein the test fields are covered by the parts of the overlay elements that can be displaced freely relative to the strip surface.
44. The test strip of claim 42 wherein the overlay comprises two overlay elements whose parts that can be displaced freely relative to the strip surface face one another and overlap.
45. The test strip of claim 44 wherein the overlap covers two test fields.
- Seq C2*
46. The test strip of claim 41 wherein the test strip comprises two single or multilayer test fields for the same or different diagnostically usable analytes, said test fields directly adjoining one another or being separated by a gap.
47. The test strip of claim 41 wherein the arrangement of detection layers and overlays on the test strip is covered with an inert flat material in such a manner that a space only remains free that is adequate for sample application in an overlap region of the overlay elements viewed in the direction of the longitudinal axis of the test strip.
48. The test strip of claim 41 wherein the hydrophilicity, transparency and liquid conducting capacity of the overlay material are matched in such a manner that a sample excess is not taken up by the strip.
49. The test strip of claim 41 wherein the test strip comprises one test field which supports a monofilament spreading material which is larger than the test field and is attached to the support on both sides of the test field by means of a spacer having the thickness of the test field whereby the part of the spreading material which extends beyond the test field is covered by sample-impermeable material

so that a sample application is only possible on that part of the spreading material which rests on the test field.

SUB C1

B2